

### **Remarks**

Applicant has amended Claims 1 and 19. Paragraph 17 of the specification supports the added limitation.

### **Rejection of Claims on Art Grounds in the 08/11/2003 Office Action, and Traversal Thereof**

In the 19 March 2004 Office Action, Claims 1-2, 6, 9-11, and 17-19 were rejected under 35 U.S.C. 103(a) as being anticipated by Campbell in view of Russo. Under 35 U.S.C. 103(a), Claims 3-5, 7-8, 12-16 were rejected as being unpatentable over Campbell and Russo and in further view of Helmer.

The above rejections of the claims 1-19 on the stated art grounds are traversed, and consideration of the patentability of the claims 1- 19, now amended, is requested, in light of the following remarks.

Applicant's invention includes a band with a pocket to receive and retain the free end of medical tube, the distal end of which is anchored in a patient. As set forth in the specification at paragraph 18 and 19, an opening in the pocket is large enough such that movement of the patient or the band with respect to the patient's skin will not cause movement to the tube when inserted into the protective pocket. In particular, the protective pocket permits and promotes some tube movement within the pocket such that movement of the patient with respect to the band or vice versa will not likely cause movement of the tube itself. The interior of the pocket or pouch is preferably made of a "slick" or low-friction surface to facilitate the sliding of the tube. Thus as the patient wears the device and moves around in daily activities, the relative movement between the patient and the free end of the

tube is concentrated at the pocket, not the end of the tube attached to the patient, so the stoma is not irritated by the movement.

### **Arguments for Patentability**

As set forth in the background section of the specification for the present invention, Campbell has shortcomings that are solved by the present invention as claimed. More specifically, Campbell discloses a band having a pouch that is secured directly to the body such that the tube is inserted into the pouch through holes in the band that directly contact the patient's skin – this directly contrasts from the present invention as claimed. The present invention includes a pocket opening positioned away from the patient's skin thus allowing a medical tube to move comfortably in concert with the patient's body. In contrast, any slippage of the Campbell-type belt-pouch will move the tube with respect to the body opening or stoma, causing irritation and discomfort, and could potentially dislodge the tube. Furthermore, Campbell teaches that the fasteners of the pouch are intended to secure the tube to the pouch in order to reduce the possibility of the tube sliding into the patient's body. However, this feature will also promote tube movement when the patient moves with respect to the belt device, or vice versa. Thus, Campbell does not disclose or suggest the protective pocket in the present invention, which allows some tube movement within the pocket such that movement of the patient with respect to the band and vice versa will not likely cause movement of the tube itself.

Helmer requires the use of a protective shield (20), which obviates the application of breathable fabric as in the present invention. This limitation only appears in Claim 4. So this argument is only applicable to Claim 4 or those where breathable is a necessary inference. Any protective shield would necessarily serve as a barrier between the patient and the

convertible receptacle of Helmer; thus if the receptacle of Helmer were breathable, it would not functionally be breathable when c Helmer cannot be combined with Campbell inasmuch as Helmer's shield would block the insertion of the tube via holes in the belt of Campbell.

Furthermore, the ties of Helmer could not possibly be combined with the invention of Campbell, since the rectangular band of Campbell necessarily is constructed and configured to provide for connection via overlapping hood and loop fasteners, namely mating fasteners (see Campbell col. 5 lines 30-45) to provide a solid band for securing directly onto the midsection of a patient. Ties were known at the time of Campbell and were expressly not included, since tying the ends would prevent the formation of the pouch section and would further introduce problems of belt movement or slippage that would certainly disrupt or dislodge the tubes and irritate the stoma, thereby rendering the belt of Campbell non-functional were ties added.

The applicant respectfully asserts that the examiner has combined the references of Campbell and Helmer in hindsight based upon the claims of the present invention, which is improper. It is unreasonable to consider the combination of two references where significant or key elements of one invention would render the other invention non-functional.

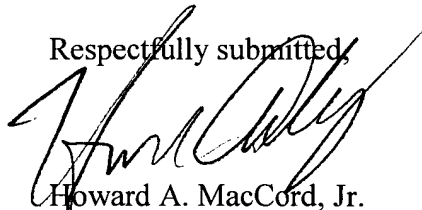
The Examiner further cites Russo in combination with Campbell as making the claimed invention obvious. Russo describes a device designed to hold medical devices such as medical tubes and wound drainage bulbs. The medical device holder in Russo consists of a strap that extends around the patient's midsection and two layers of material attached to the strap that can be fastened together into a pouch to secure the medical device. Although it may appear on the surface that the device holder in Russo and the present invention are substantially similar, the present invention provides an open-ended pouch with a low-friction

inner lining to promote movement of a medical tube within the pocket. In contrast, the inner surfaces of both the front layer and the rear layer of the Russo pouch are covered with a loop material, thereby securing the tube in place within the pouch and thus prevents little if any lateral movement or shifting of the tube inserted therein. (see Russo col. 2 lines 60-65 and col.3 lines 16-18) If the tube end in the pouch cannot move, then any movement must be transmitted to the stoma causing irritation. In contrast, the present invention greatly enhances the comfort level provided to the patient over prior art by avoiding the tugging and agitation that is produced by a medical tube holder that does not allow freedom of movement within the pouch.

Claims 1-19, now amended, are asserted to be in patentable condition. Allowance of these claims is hereby respectfully requested. In the event that the Examiner finds additional minor modifications that would place these claims in allowable condition, the Examiner is respectfully requested to make telephonic contact with the Attorney of Record to discuss and make changes via Examiner's Amendment to place the claims in condition for allowance.

The above rejections of the claims 1-19 on the stated art and utility grounds are traversed, and consideration of the patentability of the claims 1-19 is requested, in light of the foregoing remarks. Favorable action is therefore requested.

Respectfully submitted,



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